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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,882	DUFF ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 November 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/12/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claim Objections

1. Claim 2 is objected to because of the following informalities:

In claim 2, a "." should be inserted after "(SEQ ID NO: 10)".

In claim 2, SEQ ID NO: 1 is identical to SEQ ID NO: 9 and SEQ ID NO: 8 is identical to SEQ ID NO: 10. The claim should be amended to delete the duplicate recitations of the sequences.

Specification

2. The disclosure is objected to because of the following informalities:

On page 23 of the specification, the statement "[There was text missing here in the original UK filing]" should be deleted and the phrase "with 1.7mM..." should be amended to recite a complete sentence.

On page 31 of the specification, the statement "Michelson, 1940 [need citation]" is not complete.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,713,253. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers of SEQ ID NO: 1-10. The claims of '253 are drawn to methods which require the use of the reagents of a means for isolating a DNA sample and the primers of SEQ ID NO: 1-10. The claims of '253 do not specifically recite packaging the collection means and primers into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers and collection means of '253 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1RN (VNTR), IL-1A (-511) and IL-1B (-889) polymorphisms.

As noted in the MPEP 211.02, " a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets

forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation". In the present situation, the claim language of "for the identification of a diabetic patient's genetic polymorphism pattern" is a statement of purpose and intended result and does further limit the scope of the claims. Accordingly, the structural elements of the kit are able to stand alone and therefore the preamble limitation is not accorded patentable weight.

4. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,733,967. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme or a primer of SEQ ID NO: 3 and 4. The claims of '967 are drawn to methods which require the use of the reagents of a means for obtaining a DNA sample, amplification reagents and the restriction enzymes AvaI and NcoI. It is noted that the means for amplifying a DNA sample as claimed in '967 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '967 do not specifically recite packaging a means for collecting a DNA sample, primers and/or restriction enzymes into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made to have packaged the primers, amplification reagents, restriction enzymes and a DNA sample collection means in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

5. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,140,047. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme or a primer of SEQ ID NO: 1 and 3-10. The claims of '047 are drawn to kits which include a means for collecting a DNA sample, a primer for detecting the IL-1B (–511) polymorphism and an AvaI or Bsu36I polymorphism. Accordingly, the kits of present claims 1 and 3 are obvious in view of the kits of '047 containing the same set of reagents. Further, the claims of '047 include methods which require the use of a reagent for collecting a DNA sample, amplification reagents and primers which are identical to present SEQ ID NO: 3 and 4 (also referred to therein as SEQ ID NO: 3 and 4). It is noted that the means for amplifying a DNA sample as claimed in '047 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511)

and IL-1RN." The claims of '047 do not specifically recite packaging the primers of SEQ ID NO: 3 and 4 in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of SEQ ID NO: 3 and 4 in a kit together with the means for obtaining a DNA sample and amplification reagents for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

6. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,686,246. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '246 are drawn to kits and nucleic acid detection methods which require the use of primers for detecting the IL-1A (-889) and IL-1B (-511) polymorphisms (including primers identical to present SEQ ID NO: 7 and 8; referred to as SEQ ID NO: 1 and 2 therein), and restriction enzymes of NcoI, AvaI and Bsu36I. The kits of '246 also require a DNA sampling means. Further, the kits of '246 include a means for amplifying a DNA sample. It is noted that the means for amplifying a DNA sample as claimed in '246 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN."

It is further noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

7. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,720,141. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme or a primer of SEQ ID NO: 1 and 3-10. The claims of '141 are drawn to methods which require the use of the reagents of a means for obtaining a DNA sample, means for amplifying a DNA sample, the restriction enzymes AvaI, NcoI and Bsu36I and the primers of present SEQ ID NO: 1, and 3-10 (referred to therein as SEQ ID NO: 3, 4, 7, 8, 13 and 14). It is noted that the means for amplifying a DNA sample as claimed in '141 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '141 do not specifically recite packaging a means for collecting a DNA sample, means for amplifying a DNA sample, restriction enzymes and/or primers into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the restriction enzymes, primers, amplification reagents and a DNA sample collection

means in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1 polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

8. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,210,877. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme or a primer of SEQ ID NO: 3-6. The claims of '877 are drawn to methods which require the use of the reagents of a means for obtaining a DNA sample, means for amplifying a DNA sample, and the primers of present SEQ ID NO: 3-6 (referred to therein as SEQ ID NO: 1-4). The claims of '877 further require the use of a restriction enzyme to detect a IL-1B (-511) polymorphism. The claims of '877 are read in light of the specification wherein said means is defined as including the restriction enzymes of AvaI and Bsu36I. It is noted that the means for amplifying a DNA sample as claimed in '877 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '877 do not specifically recite packaging a means for collecting a DNA sample, restriction enzymes and/or primers into a kit. However, reagent kits for performing DNA detection assays were conventional

in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the restriction enzymes, primers, amplification reagents and a DNA sample collection means in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect the IL-1B (-511) and IL-1RN (VNTR) polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

9. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6,746,839. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme or a primer of SEQ ID NO: 1, 3-6 and 8-10. The claims of '839 are drawn to methods and kits which require the use of the reagents for obtaining a DNA sample, amplification reagents and the primers of present SEQ ID NO: 1, 3-6 and 8-10 (referred to therein as SEQ ID NO: 10-14, 17 and 18). The claims of '839 further require the use of the restriction enzymes of NcoI, AvaI and Bsu36I. It is noted that the means for amplifying a DNA sample as claimed in '839 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN."

The claims of '839 do not specifically recite including the restriction enzymes in the claimed kits, together with a means for collecting a sample DNA and/or primers. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the restriction enzymes, primers and a DNA sample collection means in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect the IL-1B (-511), IL-1A (-889) and IL-1RN (VNTR) polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

10. Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,698,399. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers of SEQ ID NO: 5 and 6. The claims of '399 are drawn to methods which require the use of the reagents of a means for isolating a DNA sample, a means for amplifying a DNA sample and the primers identical to present SEQ ID NO: 5 and 6 (referred to as SEQ ID NO: 1 and 2 therein). It is noted that the means for amplifying a DNA sample as claimed in '399 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '399 do not specifically recite packaging the collection means and primers into a kit. However, reagent kits for performing DNA detection assays were conventional in the

field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers, amplification reagents and collection means of '399 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1 polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

11. Claims 1 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,524,795. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI, NcoI or Bsu36I restriction enzyme. The claims of '795 are drawn to methods which require the use of the reagents of a means for obtaining a DNA sample, amplification means and the restriction enzymes AvaI, NcoI and Bsu36I. It is noted that the means for amplifying a DNA sample as claimed in '795 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '795 do not specifically recite packaging the collection means and restriction enzymes into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have

been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the restriction enzymes, amplification means and collection means of '795 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1 polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

12. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,268,142. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be a primer of SEQ ID NO: 5, 6 or 8. The claims of '142 are drawn to kits which include a primer that is identical to present SEQ ID NO: 5, 6 or 8 (referred to therein as SEQ ID NO: 13, 22 and 23). The claims of '142 do not recite the inclusion of a collection means or amplification means. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged a DNA collection means and amplification means together with the primers in order to have facilitated the isolation and collection of DNA in methods for detecting the IL-1 polymorphisms. Further, the claims of '142 include methods which require the use of a reagent for collecting a DNA sample, amplification means and primers which are identical to present SEQ ID NO: 5, 6 and 8,

as well as restriction enzymes for detecting the IL-1B (-511) and IL-1A (-889) polymorphisms. The claims of '142 are read in light of the specification wherein said restriction endonucleases are defined as AvaI, Bsu36I and NcoI. Further, it is noted that the means for amplifying a DNA sample as claimed in '142 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included the restriction enzymes in the kit of '142 in order to have provided an effective and simple means for detecting the the IL-1B (-511) and IL-1A (-889) polymorphisms

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

13. Claims 1 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,251,598. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be an AvaI or Bsu36I restriction enzyme. The claims of '598 are drawn to methods which require the use of the reagents of a means for obtaining a DNA sample, means for amplifying a DNA sample and the restriction enzymes AvaI, NcoI and Bsu36I. It is noted that the means for amplifying a DNA sample as claimed in '399 constitutes a means for "determining a

genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '598 do not specifically recite packaging the DNA sample collection means, amplification reagents and restriction enzymes into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the restriction enzymes, amplification reagents and collection means of '598 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect IL-1B (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

14. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,706,478. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein the means for determining the genetic polymorphism pattern may be a primer of SEQ ID NO: 5, 6 or 8. The claims of '478 include methods which require the use of a reagent for collecting a DNA sample, amplification means and primers which are identical to present SEQ ID NO: 5, 6 and 8 (referred to therein as SEQ ID NO: 13, 22 and 23), as well as restriction endonucleases for detecting the IL-1B (-511) and IL-1A (-889) polymorphisms. The

claims of '478 are read in light of the specification wherein said restriction endonucleases are defined as AvaI, Bsu36I and NcoI. Further, it is noted that the means for amplifying a DNA sample as claimed in '478 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '478 do not specifically recite packaging the DNA sample collection means, primers and restriction enzymes into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers, restriction enzymes and collection means of '478 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect the the IL-1B (-511) and IL-1A (-889) polymorphisms

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

15. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-21 of copending U.S. Application No. 10/320,360. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers of SEQ ID NO: 3 and 4 for the detection of the IL-1B (–511) polymorphism or the restriction enzymes of AvaI and Bsu36I. The claims of '360 are drawn to kits comprising a means for detecting the IL-1B

(-511) polymorphism. The claims '360 have been read in light of the specification and the specification therein defines the means for detecting the IL-1B (-511) polymorphism as including primers identical to present SEQ ID NO: 3 and 4 and the restriction enzymes of AvaI and Bsu36I. The kits of '360 do not specifically recite including a DNA collection means or amplification means in the kit. It is noted that the means for amplifying a DNA sample as claimed in '360 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits of '360 so as to have further included a means for collecting sample DNA and amplification means together with the primers in the kit in order to have allowed practioners a convenient means for obtaining the sample DNA to be assayed for the presence of a IL-1B (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending U.S. Application No. 10/914,396. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers of SEQ ID NO: 3 and 4 for

the detection of the IL-1B (–511) polymorphism or the restriction enzymes of AvaI and Bsu36I. The claims of '396 are drawn to kits comprising a means for detecting the IL-1B (-511) polymorphism and amplification means. The claims '396 have been read in light of the specification and the specification therein defines the means for detecting the IL-1B (-511) polymorphism as including primers identical to present SEQ ID NO: 3 and 4 and the restriction enzymes of AvaI and Bsu36I. Further, it is noted that the means for amplifying a DNA sample as claimed in '396 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The claims of '396 also include methods for detecting the IL-1B (-511) polymorphism wherein the methods require the use of the reagents of an amplification means, primers and restriction enzymes. The claims of '396 do not specifically recite including a DNA collection means in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits of '396 so as to have further included a means for collecting sample DNA in order to have allowed practioners a convenient means for obtaining the sample DNA to be assayed for the presence of a IL-1B (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending U.S. Application No. 10/838,503. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers of SEQ ID NO: 1, 3-6 and 8-10 or the restriction enzymes of NcoI, AvaI and Bsu36I. The claims of '503 are drawn to kits comprising a means for detecting the IL-1B (-511), IL-1A (-889) and IL-1RN (VNTR) polymorphisms. The claims of '503 require a DNA sampling (i.e., collection) means and primers that are identical to present SEQ ID NO: 1, 3-6 and 8-10. Further, the claims of '503 require a means for detecting DNA. The claims '503 have been read in light of the specification and the specification therein defines the means for detecting DNA containing the IL-1B (-511) or IL-1A (-889) polymorphism as including amplification reagents and the restriction enzymes of AvaI, Bsu36I and NcoI. It is noted that the means for amplifying a DNA sample as claimed in '503 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the restriction enzymes of AvaI, Bsu36I and NcoI in the kit in order to have provided means for facilitating the detection of the IL-1B (-511) and IL-1A (-889) polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15 of copending U.S. Application No. 10/823,197. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and the primers for the detection of IL-1A (-511) polymorphism. The claims of '197 are drawn to kits comprising amplification means and a means for detecting the IL-1RN (VNTR) polymorphism, wherein said means includes a primer consisting of the same sequence as present SEQ ID NO: 5 and 6. Further, the claims of '197 require a means for detecting DNA. The claims '197 have been read in light of the specification and the specification therein defines the means for detecting DNA containing the IL-1B (-511) polymorphism as including amplification reagents and the restriction enzymes of AvaI, and Bsu36I. It is noted that the means for amplifying a DNA sample as claimed in '197 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." The kits of '197 do not specifically recite including a DNA collection means in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits of '197 so as to have further included a means for collecting sample DNA in order to have allowed practioners a convenient means for obtaining the sample DNA to be assayed for the presence of the IL-1A (-511) polymorphism.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending U.S. Application No.10/843,493. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to kits comprising a DNA collection means and a means for detecting the IL-1 polymorphism, wherein said means is a primer of SEQ ID NO: 1, 3-10 or the restriction enzymes of NcoI, AvaI and Bsu36I. The claims of '493 are drawn to kits comprising a means for detecting the IL-1B (-511) and IL-1A (-889) polymorphisms, wherein said means is a primer identical to present SEQ ID NO: 1 and 3-10. Further, the claims of '493 require a means for detecting DNA. The claims '493 have been read in light of the specification and the specification therein defines the means for detecting DNA containing the IL-1B (-511) or IL-1A (-889) polymorphism the restriction enzymes of AvaI, Bsu36I and NcoI. Additionally, the claims of '493 recite the inclusion of amplification reagents in the kit. It is noted that the amplification reagents as claimed in '493 constitutes a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the restriction enzymes of AvaI, Bsu36I and NcoI

in the kit in order to have provided means for facilitating the detection of the IL-1B (-511) and IL-1A (-889) polymorphisms. Further, the kits of '493 do not specifically recite including a DNA collection means in the kit. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the kits of '493 so as to have further included a means for collecting sample DNA in order to have allowed practioners a convenient means for obtaining the sample DNA to be assayed for the presence of the IL-1 polymorphisms.

It is noted that, as discussed above, the intended use of the kit for "the identification of a diabetic patient's genetic polymorphism pattern" does not carry weight with respect to the obviousness of the kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 rejected under 35 U.S.C. 102(e) as being anticipated by Rothberg (U.S. Patent No. 6,418,382).

Rothberg (e.g., paragraph 122-123; and claims 6 and 16)) discloses kits wherein the kits include one or more containers that comprise the restriction enzyme NcoI (a means for determining a genetic polymorphism pattern) and reagents for performing a cDNA sample preparation step. The containers containing cDNA sample preparation reagents are considered to constitute "DNA sample collecting means" because the reagents that are utilized for cDNA sample preparation are useful for accomplishing the step of sample collection. For instance, Rothberg (paragraph 329) teaches that the cDNA is prepared in a process that involves isolation of RNA using a magnetic bead with an oligo(dT) capture moiety, synthesis of cDNA by reverse transcriptase and isolation of the newly synthesized cDNA. Additionally, the containers disclosed by Rothberg constitute DNA sample collection means. Accordingly, the kits of Rothberg contain both a DNA sample collecting means and a means for determining a genetic polymorphism pattern.

As noted in the MPEP 211.02, " a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation". In the present

situation, the claim language of "for the identification of a diabetic patient's genetic polymorphism pattern" is a statement of purpose and intended result and does further limit the scope of the claims. Accordingly, the structural elements of the kit are able to stand alone and therefore the preamble limitation is not accorded patentable weight.

21. Claims 1-3 rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Kornman (U.S. Patent No. 5,686,246).

Kornman (e.g., paragraphs 1, 14 and 18 and claim 9) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of NcoI, AvaI and Bsu36I (see, e.g., paragraphs 5 and 31). In particular, Kornman teaches that the primers used for detecting the IL-1A (-889) and IL-1B (-511) polymorphisms include primers identical to present SEQ ID NO: 7 and 8 (referred to therein as SEQ ID NO: 1 and 2). It is noted that the amplification reagents of Kornman have the property of being a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, Kornman teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 7 and 8 and the restriction enzymes of NcoI, AvaI and Bsu36I.

22. Claims 1-3 rejected under 35 U.S.C. 102(e) as being anticipated by Duff et al (U.S. Patent No. 6,140,047).

Duff (e.g., paragraphs 27-28 and 57) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of AvaI and Bsu36I (see, e.g., paragraphs 12 and 20). In particular, Duff teaches that the primers used for detecting IL-1B (-511) polymorphisms include primers identical to present SEQ ID NO: 3 and 4 (referred to therein as SEQ ID NO: 3 and 4). It is noted that the amplification reagents of Duff have the property of being a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, Duff teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 3 and 4 and the restriction enzymes of AvaI and Bsu36I.

23. Claims 1-3 rejected under 35 U.S.C. 102(e) as being anticipated by Duff et al (U.S. Patent No. 6,746,839).

Duff (e.g., paragraphs 26, 27 and 84) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of AvaI and Bsu36I (see, e.g., paragraphs 151 and 183). In particular, Duff teaches that the primers used for detecting IL-1B (-511) polymorphisms include primers identical to present SEQ ID NO: 3 and 4 (referred to therein as SEQ ID NO: 10 and 11). It is noted that the amplification reagents of Duff have the property of being a means for "determining a genetic polymorphism

pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, Duff teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 3 and 4 and the restriction enzymes of AvaI and Bsu36I.

24. Claims 1-3 rejected under 35 U.S.C. 102(e) as being anticipated by Francis et al (U.S. Patent No. 6,210,877).

Francis (e.g., paragraphs 26 and 29) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of AvaI and Bsu36I (see, e.g., paragraphs 36 and 47). In particular, Francis teaches that the primers used for detecting IL-1B (-511) and IL-1A (-889) polymorphisms include primers identical to present SEQ ID NO: 3-6 (referred to therein as SEQ ID NO: 1-4). It is noted that the amplification reagents of Duff have the property of being a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, Francis teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 3-6 and the restriction enzymes of AvaI and Bsu36I.

25. Claims 1-3 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/320,360 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35

U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Application '360 (see, e.g., paragraphs 0037-0040) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of AvaI and Bsu36I (paragraph 0261). In particular, the '360 application teaches that the primers used for detecting IL-1B (-511) and IL-1A (-889) polymorphisms include primers identical to present SEQ ID NO: 3-6 (referred to therein as SEQ ID NO: 1-4). It is noted that the amplification reagents have the property of being a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, the '036 application teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 3-6 and the restriction enzymes of AvaI and Bsu36I.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

26. Claims 1-3 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/823,197 which has a common inventor with the instant

application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Application '197 (see, e.g., paragraphs 0174-0175) discloses kits comprising a DNA collection means and a means for determining a genetic polymorphism pattern, wherein said means for determining a genetic polymorphism pattern are defined as including primers, amplification reagents and the restriction enzymes of AvaI and Bsu36I (see, e.g., table 10). In particular, the '197 application teaches that the primers used for detecting IL-1B (-511) and IL-1A (-889) polymorphisms include primers identical to present SEQ ID NO: 3-6 (referred to therein as SEQ ID NO: 1-4). It is noted that the amplification reagents have the property of being a means for "determining a genetic polymorphism pattern for IL-1A (-899), IL-1B (-511) and IL-1RN." Accordingly, the '197 application teaches kits comprising a collection means, a means for determining the genetic pattern of IL-1A (-899), IL-1B (-511) and IL-1RN, the primers of present SEQ ID NO: 3-6 and the restriction enzymes of AvaI and Bsu36I.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansfield (Gastroenterology (1994) 106:637-642; cited in the IDS) .

Mansfield teaches methods for detecting polymorphisms at position -511 of the IL-1B gene and at position -889 of the IL-1A gene and for detecting VNTR alleles of IL-1 RN. In the method disclosed by Mansfield, PCR is performed using primers complementary to sequences flanking the -511 allele of IL-1B which consist of the same sequences as instant SEQ ID NO: 3 and 4, primers complementary to sequences flanking the -889 allele of IL-1A which consist of the sequences identical to instant SEQ ID NO: 9 and 10 and primers complementary to sequences flanking the VNTR allele of

IL-1 RN which consist of sequences identical to instant SEQ ID NO: 5 and 6 (see Table 2). The method of Mansfield further requires the use of reagents for performing PCR including a means for collecting DNA. Accordingly, Mansfield teaches a method which requires the use of reagents for the primers of SEQ ID NO: 3, 4, 5, 6, 9 and 10 and a DNA collection means. Additionally, the amplification reagents, such as polymerase, disclosed by Mansfield are also considered to be a means for determining the genetic polymorphism pattern for IL-1A (-889), IL-1B (-511) and IL-1RN (VNTR) because the amplification reagents allow for the amplification of sequences containing the stated polymorphisms. Mansfield does not teach packaging these reagents into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made and therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers, DNA polymerase and DNA collection means required to practice the method of Mansfield into a kit for the expected benefits of convenience and cost-effectiveness for practioners of methods for detecting IL-1 RN (VNTR), IL-1A (-889) and IL-1B (-511) polymorphisms.

It is noted that in claims to products, such as kits, the intended use of the product does not carry weight with respect to the obviousness of the product. As stated in MPEP 211.02, "When the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property in the old composition. *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 480-481". The MPEP (2112) further states that "the claiming of a new use,

new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable".

28. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mansfield in view of Kornman (U.S. Patent 5,686,246; cited in the IDS).

Mansfield teaches methods for detecting polymorphisms at position -511 of IL-1B and at position -889 of IL-1A and for detecting VNTR alleles of IL-1 RN. In the method disclosed by Mansfield, PCR is performed using primers complementary to sequences flanking the -511 allele of IL-1B which consist of the same sequences as instant SEQ ID NO: 3 and 4, primers complementary to sequences flanking the -889 allele of IL-1A which consist of the same sequences as instant SEQ ID NO: 9 and 10 and primers complementary to sequences flanking the VNTR allele of IL-1 RN which consist of the same sequences as instant SEQ ID NO: 5 and 6 (see Table 2). The method of Mansfield also requires the use of reagents required to perform PCR including a means for collecting DNA and DNA amplification means. Mansfield (page 639) further teaches that the IL-1A (-889) polymorphism may be detected by restriction enzyme digestion with *NcoI* and the IL-1B (-511) polymorphism may be detected by restriction enzyme digestion with *AvaI*. Mansfield does not teach detecting the IL-1B (-511) polymorphism using the restriction enzyme *Bsu36I* and does not teach packaging the reagents required to detect the polymorphisms into a kit.

However, Kornman (col. 6) teaches that the IL-1B (-511) polymorphism may be detected using the restriction enzyme *Bsu36I* and specifically teaches that allele 2 of IL-1B (-511) contains a complete *Bsu36I* site. Accordingly, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to have modified the method of Mansfield so as to have also detected allele 2 of the IL-1B (-511) polymorphism by digestion with *Bsu36I* because Kornman teaches that this is an effective means for directly detecting the presence of IL-1B (-511) allele 2. The resulting modified method of Mansfield thereby requires the use of reagents for collecting a DNA sample, the primers of SEQ ID NO: 1, 2, 3, 4, 9 and 10, and the restriction enzymes *NcoI, AvaI* and *Bsu36I*. In view of the conventionality of reagent kits for performing DNA detection, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the DNA collection means, restriction enzymes and primers required to practice the method of Mansfield into a kit for the expected benefits of convenience and cost-effectiveness for practioners of methods for detecting IL-1 RN (VNTR), IL-1A (-889) and IL-1B (-511) polymorphisms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers

October 12, 2005

CARLA J. MYERS
PRIMARY EXAMINER